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(54) **FACET DEVICE AND METHOD**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,774,350	A	9/1952	Cleveland
3,242,922	A	3/1966	Thomas

(Continued)

FOREIGN PATENT DOCUMENTS

DE	2644735	A1	4/1977
DE	2845647	A1	5/1980

(Continued)

OTHER PUBLICATIONS

English translation of DE10135771A1.*

(Continued)

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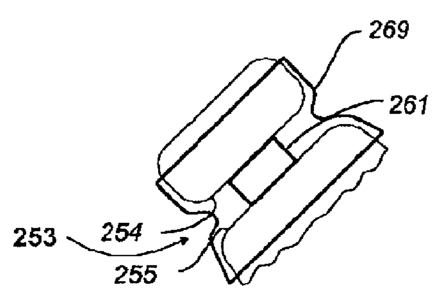
(57) **ABSTRACT**

A spine implant includes an insert positioned between facets of a zygapophyseal joint. In various embodiments, the insert is configured to exert a distraction force on one or more facets of the zygapophyseal joint. The insert may comprise one or more members having one or more opposing facet interfacing portions. A securing member is configured to interface with the insert to secure the facets.

15 Claims, 6 Drawing Sheets



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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,352,226 A 11/1967 Nelsen
3,648,691 A 3/1972 Lumb et al.
3,693,616 A 9/1972 Roaf et al.
3,865,105 A 2/1975 Lode
4,024,588 A 5/1977 Janssen et al.
4,078,559 A 3/1978 Nissinen
4,257,409 A 3/1981 Bacal et al.
4,269,178 A 5/1981 Keene
4,274,401 A 6/1981 Miskew
4,355,645 A 10/1982 Mitani et al.
4,361,141 A 11/1982 Tanner
4,369,769 A 1/1983 Edwards
4,404,967 A 9/1983 Bacal et al.
4,411,259 A 10/1983 Drummond
4,411,545 A 10/1983 Roberge
4,448,191 A 5/1984 Rodnyansky et al.
4,505,268 A 3/1985 Sgandurra
4,554,914 A 11/1985 Kapp et al.
4,573,454 A 3/1986 Hoffman
4,604,995 A 8/1986 Stephens et al.
4,611,581 A 9/1986 Steffee
4,611,582 A 9/1986 Duff
4,634,445 A 1/1987 Helal
4,648,388 A 3/1987 Steffee
4,653,481 A 3/1987 Howland et al.
4,658,809 A 4/1987 Ulrich et al.
4,697,582 A 10/1987 William
4,738,251 A 4/1988 Plaza
4,773,402 A 9/1988 Asher et al.
4,805,602 A 2/1989 Puno et al.
4,815,453 A 3/1989 Cotrel
4,827,918 A 5/1989 Olerud
4,854,311 A 8/1989 Steffee
4,931,055 A 6/1990 Bumpus et al.
4,936,848 A 6/1990 Bagby
5,000,166 A 3/1991 Karpf
5,005,562 A 4/1991 Cotrel
5,011,484 A 4/1991 Breard
5,030,220 A 7/1991 Howland
5,042,982 A 8/1991 Harms et al.
5,084,049 A 1/1992 Asher et al.
5,092,866 A 3/1992 Breard et al.
5,092,867 A 3/1992 Harms et al.
5,125,408 A * 6/1992 Basser A61B 5/03
600/410
5,127,912 A 7/1992 Ray et al.
5,129,900 A 7/1992 Asher et al.
5,133,716 A 7/1992 Plaza
5,147,363 A 9/1992 Harle
5,176,679 A 1/1993 Lin
5,176,680 A 1/1993 Vignaud et al.
5,181,917 A 1/1993 Rogozinski
5,190,543 A 3/1993 Schlapfer
5,196,014 A 3/1993 Lin
5,207,678 A 5/1993 Harms et al.
5,209,752 A 5/1993 Ashman et al.
5,219,349 A 6/1993 Krag et al.
5,242,443 A 9/1993 Kambin
5,254,118 A 10/1993 Mirkovic
5,257,994 A 11/1993 Lin
5,259,398 A 11/1993 Vrespa
5,282,862 A 2/1994 Baker et al.
5,306,275 A 4/1994 Bryan
5,312,404 A 5/1994 Asher et al.
5,312,410 A 5/1994 Miller et al.
5,312,420 A 5/1994 Toso et al.
5,330,473 A 7/1994 Howland
5,330,474 A 7/1994 Lin
5,352,226 A 10/1994 Lin
5,360,431 A 11/1994 Puno et al.
5,366,455 A 11/1994 Dove et al.
5,368,594 A 11/1994 Martin et al.
5,380,323 A 1/1995 Howland
5,380,325 A 1/1995 Lahille et al.
5,382,248 A 1/1995 Jacobson et al.
5,387,212 A 2/1995 Yuan et al.
5,387,213 A 2/1995 Breard et al.
5,391,168 A 2/1995 Sanders et al.
5,397,363 A 3/1995 Gelbard
5,413,576 A 5/1995 Rivard
5,436,542 A 7/1995 Petelin et al.
5,437,669 A 8/1995 Yuan et al.
5,437,671 A 8/1995 Lozier et al.
5,456,722 A 10/1995 McLeod et al.
5,456,724 A * 10/1995 Yen A61B 5/224
600/594
5,466,238 A 11/1995 Lin
5,470,333 A 11/1995 Ray
5,480,440 A 1/1996 Kambin
5,486,174 A 1/1996 Fournet-Fayard et al.
5,487,744 A 1/1996 Howland
5,490,851 A 2/1996 Nenov et al.
5,496,318 A 3/1996 Howland et al.
5,498,262 A 3/1996 Bryan
5,501,684 A 3/1996 Schlapfer et al.
5,520,688 A 5/1996 Lin
5,527,314 A 6/1996 Brumfield et al.
5,534,002 A 7/1996 Brumfield et al.
5,540,689 A 7/1996 Sanders et al.
5,544,993 A 8/1996 Harle
5,549,679 A 8/1996 Kuslich
5,562,660 A 10/1996 Grob
5,562,662 A 10/1996 Brumfield et al.
5,569,246 A 10/1996 Ojima et al.
5,571,191 A 11/1996 Fitz
5,575,791 A 11/1996 Lin
5,584,626 A 12/1996 Assmundson
5,586,983 A 12/1996 Sanders et al.
5,591,165 A 1/1997 Jackson
5,601,554 A 2/1997 Howland et al.
5,609,592 A 3/1997 Brumfield et al.
5,611,800 A 3/1997 Davis et al.
5,620,443 A 4/1997 Gertzbein et al.
5,630,816 A 5/1997 Kambin
5,643,259 A 7/1997 Sasso et al.
5,645,599 A 7/1997 Samani
5,649,926 A 7/1997 Howland
5,658,284 A 8/1997 Sebastian et al.
5,672,175 A 9/1997 Martin
5,676,703 A 10/1997 Gelbard
5,702,395 A 12/1997 Hopf
5,702,399 A 12/1997 Kilpela et al.
5,702,452 A 12/1997 Argenson et al.
5,704,936 A 1/1998 Mazel
5,713,898 A 2/1998 Stucker et al.
5,716,355 A 2/1998 Jackson et al.
5,720,746 A 2/1998 Soubeiran
5,725,582 A 3/1998 Bevan et al.
5,728,097 A 3/1998 Mathews
5,733,284 A 3/1998 Martin
5,735,852 A 4/1998 Amrein et al.
5,782,831 A 7/1998 Sherman et al.
5,797,910 A 8/1998 Martin
5,810,817 A 9/1998 Roussouly et al.
5,810,819 A 9/1998 Errico et al.
5,814,046 A 9/1998 Hopf
5,885,285 A 3/1999 Simonson
5,891,145 A 4/1999 Morrison et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,902,305	A	5/1999	Beger et al.
5,910,142	A	6/1999	Tatar
5,928,232	A	7/1999	Howland et al.
5,938,663	A	8/1999	Petreto
5,947,967	A	9/1999	Barker
5,964,769	A	10/1999	Wagner et al.
5,976,135	A	11/1999	Sherman et al.
5,980,521	A	11/1999	Montague et al.
5,984,924	A	11/1999	Asher et al.
5,989,256	A	11/1999	Kuslich et al.
6,015,409	A	1/2000	Jackson
6,033,412	A	3/2000	Losken et al.
6,039,738	A	3/2000	Sanders et al.
6,053,921	A	4/2000	Wagner et al.
6,066,140	A	5/2000	Gertzbein et al.
6,077,268	A	6/2000	Farris et al.
6,080,156	A	6/2000	Asher et al.
6,083,224	A	7/2000	Gertzbein et al.
6,086,590	A	7/2000	Margulies et al.
6,101,678	A	8/2000	Malloy et al.
6,110,173	A	8/2000	Thomas, Jr.
6,123,706	A	9/2000	Lange
6,132,431	A	10/2000	Nilsson et al.
6,132,464	A	10/2000	Martin
6,136,000	A	10/2000	Louis et al.
6,176,861	B1	1/2001	Bernstein et al.
6,231,575	B1	5/2001	Krag
6,248,106	B1	6/2001	Ferree
6,251,111	B1	6/2001	Barker et al.
6,254,603	B1	7/2001	Gertzbein et al.
6,261,288	B1	7/2001	Jackson
6,273,914	B1	8/2001	Papas
6,277,120	B1	8/2001	Lawson
6,283,967	B1	9/2001	Troxell et al.
6,293,949	B1	9/2001	Justis et al.
6,296,643	B1	10/2001	Hopf et al.
6,299,613	B1	10/2001	Ogilvie et al.
6,325,805	B1	12/2001	Ogilvie et al.
6,328,739	B1	12/2001	Liu et al.
6,358,254	B1	3/2002	Anderson
6,364,883	B1	4/2002	Santilli
6,364,885	B1	4/2002	Kilpela et al.
6,379,357	B1	4/2002	Bernstein et al.
6,391,030	B1	5/2002	Wagner et al.
6,402,749	B1	6/2002	Ashman
6,402,752	B2	6/2002	Schaffler-Wachter et al.
6,419,703	B1	7/2002	Fallin et al.
6,423,065	B2	7/2002	Ferree
6,425,920	B1 *	7/2002	Hamada A61B 17/1604 623/17.16
6,447,448	B1 *	9/2002	Ishikawa A61B 5/0031 128/899
6,451,019	B1	9/2002	Zucherman et al.
6,458,131	B1	10/2002	Ray
6,471,704	B2	10/2002	Gertzbein et al.
6,478,822	B1 *	11/2002	Leroux A61F 2/442 623/17.14
6,482,234	B1 *	11/2002	Weber A61F 2/441 623/17.12
6,488,683	B2	12/2002	Lieberman
6,514,255	B1	2/2003	Ferree
6,520,962	B1	2/2003	Taylor et al.
6,537,276	B2	3/2003	Metz-Stavenhagen
6,547,789	B1	4/2003	Ventre et al.
6,551,320	B2	4/2003	Lieberman
6,554,831	B1	4/2003	Rivard et al.
6,562,038	B1	5/2003	Morrison
6,565,569	B1	5/2003	Assaker et al.
6,565,605	B2	5/2003	Goble et al.
6,569,164	B1	5/2003	Assaker et al.
6,579,292	B2	6/2003	Taylor
6,579,319	B2	6/2003	Goble et al.
6,582,433	B2	6/2003	Yun
6,585,738	B1	7/2003	Mangione et al.
6,589,243	B1	7/2003	Viart et al.
6,602,254	B2	8/2003	Gertzbein et al.
6,602,818	B2	8/2003	Choi et al.
6,610,091	B1	8/2003	Reiley
6,616,669	B2	9/2003	Ogilvie et al.
6,623,484	B2	9/2003	Betz et al.
6,626,906	B1	9/2003	Young
6,626,909	B2	9/2003	Chin
6,641,585	B2	11/2003	Sato et al.
6,645,207	B2	11/2003	Dixon et al.
6,651,320	B1	11/2003	Yagi et al.
6,656,185	B2	12/2003	Gleason et al.
6,669,729	B2	12/2003	Chin
6,682,532	B2	1/2004	Johnson et al.
6,682,533	B1	1/2004	Dinsdale et al.
6,685,705	B1	2/2004	Taylor
6,689,133	B2	2/2004	Morrison et al.
6,692,495	B1 *	2/2004	Zacouto A61B 17/70 606/247
6,706,005	B2 *	3/2004	Roy A61B 5/4504 600/594
6,709,435	B2	3/2004	Lin
6,736,817	B2	5/2004	Troxell et al.
6,749,612	B1	6/2004	Conchy et al.
6,755,828	B2	6/2004	Shevtsov et al.
6,773,437	B2	8/2004	Ogilvie et al.
6,802,844	B2	10/2004	Ferree
6,811,567	B2	11/2004	Reiley
6,835,207	B2 *	12/2004	Zacouto A61B 17/68 623/17.12
6,840,127	B2	1/2005	Moran
6,860,884	B2	3/2005	Shirado et al.
6,887,241	B1	5/2005	McBride et al.
6,902,580	B2	6/2005	Fallin et al.
6,936,072	B2 *	8/2005	Lambrecht A61B 5/1076 623/17.11
6,946,000	B2	9/2005	Senegas et al.
6,966,910	B2	11/2005	Ritland
6,966,930	B2	11/2005	Arnin et al.
6,974,478	B2	12/2005	Reiley et al.
6,986,771	B2	1/2006	Paul et al.
7,008,423	B2	3/2006	Assaker et al.
7,018,379	B2	3/2006	Drewry et al.
7,029,475	B2	4/2006	Panjabi
7,041,136	B2	5/2006	Goble et al.
7,048,736	B2	5/2006	Robinson et al.
7,051,451	B2	5/2006	Augostino et al.
7,074,237	B2	7/2006	Goble et al.
7,083,621	B2	8/2006	Shaolian et al.
7,087,056	B2	8/2006	Vaughan
7,090,698	B2	8/2006	Goble et al.
7,104,992	B2	9/2006	Bailey
RE39,325	E	10/2006	Bryan
7,128,743	B2	10/2006	Metz-Stavenhagen
7,137,986	B2	11/2006	Troxell et al.
7,160,312	B2	1/2007	Saadat
7,220,262	B1	5/2007	Hynes
7,261,714	B2	8/2007	Richelsoph
7,270,665	B2	9/2007	Morrison et al.
7,290,347	B2	11/2007	Augostino et al.
7,294,129	B2	11/2007	Hawkins et al.
7,316,684	B1	1/2008	Baccelli et al.
7,335,203	B2	2/2008	Winslow et al.
7,338,490	B2	3/2008	Ogilvie et al.
7,344,539	B2	3/2008	Serhan et al.
7,361,196	B2	4/2008	Fallin et al.
7,367,978	B2	5/2008	Drewry et al.
7,406,775	B2	8/2008	Funk et al.
7,445,635	B2	11/2008	Fallin et al.
7,473,267	B2	1/2009	Nguyen et al.
7,473,269	B1	1/2009	Hynes
7,481,828	B2	1/2009	Mazda et al.
7,507,242	B2	3/2009	Triplett et al.
7,524,324	B2	4/2009	Winslow et al.
7,531,002	B2 *	5/2009	Sutton A61F 2/442 606/90
7,566,345	B1	7/2009	Fallin et al.
7,588,578	B2	9/2009	Triplett et al.
7,588,590	B2	9/2009	Chervitz et al.
7,591,836	B2	9/2009	Dick et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,594,924 B2 9/2009 Albert et al.
7,611,526 B2 11/2009 Carl et al.
7,618,453 B2 11/2009 Goble et al.
7,618,455 B2 11/2009 Goble et al.
7,621,955 B2 11/2009 Goble et al.
7,648,521 B2 1/2010 Hestad
7,658,753 B2 2/2010 Carl et al.
7,674,293 B2 3/2010 Kuiper et al.
7,678,136 B2 3/2010 Doubler et al.
7,691,130 B2 * 4/2010 Bruneau A61B 17/7062 606/249
7,691,145 B2 4/2010 Reiley et al.
7,708,762 B2 5/2010 McCarthy et al.
7,717,940 B2 5/2010 Woods et al.
7,717,942 B2 5/2010 Schumacher
7,722,647 B1 5/2010 Wang et al.
7,722,648 B2 5/2010 Drewry et al.
7,753,937 B2 7/2010 Chervitz et al.
7,758,581 B2 7/2010 Chervitz et al.
7,763,075 B2 * 7/2010 Navarro A61F 2/442 623/17.11
7,771,474 B2 8/2010 Cordaro
7,794,476 B2 9/2010 Wisnewski
7,794,478 B2 9/2010 Nilsson
7,794,499 B2 * 9/2010 Navarro A61F 2/442 600/300
7,799,054 B2 9/2010 Kwak et al.
7,819,902 B2 10/2010 Abdelgany et al.
7,824,444 B2 * 11/2010 Biscup A61F 2/442 623/17.12
7,833,252 B2 11/2010 Justis et al.
7,837,713 B2 * 11/2010 Petersen A61B 17/1757 606/247
7,837,714 B2 11/2010 Drewry et al.
7,842,071 B2 11/2010 Hawkes
7,862,586 B2 1/2011 Malek
7,896,906 B2 3/2011 Kwak et al.
7,918,876 B2 4/2011 Mueller et al.
7,927,359 B2 4/2011 Trautwein et al.
7,931,676 B2 4/2011 Veldman et al.
7,935,134 B2 5/2011 Reglos et al.
7,942,902 B2 5/2011 Schwab
7,959,653 B2 6/2011 Thramann et al.
7,963,978 B2 6/2011 Winslow et al.
7,985,243 B2 7/2011 Winslow et al.
7,985,256 B2 * 7/2011 Grotz A61F 2/442 623/17.11
7,993,269 B2 * 8/2011 Donofrio A61B 5/0031 128/903
8,012,184 B2 9/2011 Schlapfer et al.
8,016,859 B2 * 9/2011 Donofrio A61B 5/0031 606/246
8,016,860 B2 9/2011 Carl et al.
8,021,392 B2 * 9/2011 Petersen A61F 2/4405 606/247
8,021,400 B2 9/2011 Marino et al.
8,029,543 B2 10/2011 Young et al.
8,029,546 B2 10/2011 Capote et al.
8,029,566 B2 * 10/2011 Lozier A61B 17/7275 442/209
8,034,078 B2 10/2011 Laskowitz et al.
8,034,080 B2 * 10/2011 Malandain A61B 17/025 606/249
8,034,084 B2 10/2011 Landry et al.
8,043,345 B2 10/2011 Carl et al.
8,048,113 B2 11/2011 Winslow et al.
8,052,722 B2 11/2011 Winslow et al.
8,057,472 B2 11/2011 Walker et al.
8,066,743 B2 11/2011 Young et al.
8,070,775 B2 12/2011 Winslow et al.
8,070,776 B2 12/2011 Winslow et al.
8,075,594 B2 12/2011 Purcell
8,083,741 B2 * 12/2011 Morgan A61N 1/205 606/280
8,095,198 B2 * 1/2012 Nycz A61B 5/0031 600/348
8,097,022 B2 1/2012 Marik
8,114,134 B2 2/2012 Winslow et al.
8,114,158 B2 2/2012 Carl et al.
8,118,837 B2 2/2012 Lemoine
8,128,699 B2 * 3/2012 Justis A61F 2/4425 600/12
8,147,524 B2 4/2012 Piza Vallespir
8,147,549 B2 * 4/2012 Metcalf, Jr. A61B 5/0031 623/17.11
8,162,979 B2 4/2012 Sachs et al.
8,167,908 B2 5/2012 Ely et al.
8,192,471 B2 6/2012 Ludwig et al.
8,192,495 B2 * 6/2012 Simpson A61F 2/44 623/17.15
8,221,466 B2 7/2012 Asaad et al.
8,262,696 B2 9/2012 Falahee
8,292,934 B2 10/2012 Justis et al.
8,323,319 B2 12/2012 Mazda et al.
8,353,934 B2 1/2013 Drewry et al.
8,357,182 B2 1/2013 Seme
8,357,183 B2 1/2013 Seme et al.
8,361,117 B2 1/2013 Michielli et al.
8,403,958 B2 3/2013 Schwab
8,414,614 B2 4/2013 Firkins et al.
8,414,617 B2 4/2013 Young et al.
8,470,001 B2 6/2013 Trautwein et al.
RE44,392 E 7/2013 Hynes
8,475,499 B2 7/2013 Cournoyer et al.
8,480,712 B1 7/2013 Samuel et al.
8,491,572 B2 * 7/2013 Martinson A61B 5/0031 128/903
8,518,086 B2 8/2013 Seme et al.
8,636,802 B2 * 1/2014 Serhan A61B 17/7062 623/17.11
8,690,888 B2 * 4/2014 Stein A61B 17/025 606/102
8,790,278 B2 * 7/2014 Walter A61B 5/4504 600/587
8,828,058 B2 9/2014 Elsebaie et al.
8,911,448 B2 * 12/2014 Stein A61F 2/442 606/102
8,945,133 B2 * 2/2015 Stein A61B 5/107 600/424
8,956,418 B2 * 2/2015 Wasielewski A61B 5/03 600/309
8,961,571 B2 * 2/2015 Lee A61B 17/1604 606/247
8,992,620 B2 * 3/2015 Ashley A61F 2/4455 623/17.16
9,011,491 B2 4/2015 Carl et al.
9,095,436 B2 * 8/2015 Boyden A61B 17/68
2001/0037111 A1 11/2001 Dixon et al.
2002/0032442 A1 3/2002 Altarac et al.
2002/0055739 A1 5/2002 Lieberman
2002/0133155 A1 9/2002 Ferree
2002/0143329 A1 10/2002 Serhan et al.
2002/0151978 A1 10/2002 Zacouto et al.
2003/0040746 A1 2/2003 Mitchell et al.
2003/0045878 A1 3/2003 Petit et al.
2003/0093117 A1 5/2003 Saadat
2003/0109881 A1 6/2003 Shirado et al.
2003/0114853 A1 6/2003 Burgess et al.
2003/0153915 A1 8/2003 Nekozuka et al.
2003/0220643 A1 11/2003 Ferree
2004/0006391 A1 1/2004 Reiley
2004/0049274 A1 3/2004 Reiley
2004/0049277 A1 3/2004 Reiley
2004/0097931 A1 5/2004 Mitchell
2004/0106921 A1 6/2004 Cheung et al.
2004/0149065 A1 8/2004 Moran
2004/0167520 A1 8/2004 Zucherman et al.
2004/0186576 A1 * 9/2004 Biscup A61F 2/442 623/17.12
2004/0215190 A1 10/2004 Nguyen et al.
2004/0230201 A1 11/2004 Yuan et al.
2004/0230304 A1 11/2004 Yuan et al.
2005/0027361 A1 2/2005 Reiley

(56) **References Cited**

U.S. PATENT DOCUMENTS

2005/0033291 A1 2/2005 Ebara
2005/0033295 A1 2/2005 Wisnewski
2005/0043797 A1 2/2005 Lee
2005/0043799 A1 2/2005 Reiley
2005/0049705 A1 3/2005 Hale et al.
2005/0055096 A1 3/2005 Serhan et al.
2005/0080420 A1 4/2005 Farris et al.
2005/0080486 A1 4/2005 Fallin et al.
2005/0107789 A1 5/2005 Sweeney
2005/0113927 A1 5/2005 Malek
2005/0113928 A1 5/2005 Cragg et al.
2005/0131537 A1 6/2005 Hoy et al.
2005/0131538 A1 6/2005 Chervitz et al.
2005/0149030 A1 7/2005 Serhan et al.
2005/0154390 A1 7/2005 Biedermann et al.
2005/0165396 A1 7/2005 Fortin et al.
2005/0171538 A1 8/2005 Sgier et al.
2005/0177240 A1 8/2005 Blain
2005/0203509 A1 9/2005 Chinnaian et al.
2005/0203511 A1 9/2005 Wilson-MacDonald et al.
2005/0203514 A1 9/2005 Jahng et al.
2005/0203516 A1 9/2005 Biedermann et al.
2005/0209603 A1 9/2005 Zucherman et al.
2005/0216004 A1 9/2005 Schwab
2005/0228326 A1 10/2005 Kalfas et al.
2005/0228377 A1 10/2005 Chao et al.
2005/0234453 A1 10/2005 Shaolian et al.
2005/0240264 A1 10/2005 Tokish et al.
2005/0245929 A1 11/2005 Winslow et al.
2005/0261685 A1 11/2005 Fortin et al.
2005/0261770 A1 11/2005 Kuiper et al.
2005/0267470 A1 12/2005 McBride
2005/0267579 A1 12/2005 Reiley et al.
2006/0004449 A1 1/2006 Goble et al.
2006/0009767 A1 1/2006 Kiester
2006/0009847 A1 1/2006 Reiley
2006/0009849 A1 1/2006 Reiley
2006/0036246 A1 2/2006 Carl et al.
2006/0036256 A1 2/2006 Carl et al.
2006/0036259 A1 2/2006 Carl et al.
2006/0036323 A1 2/2006 Carl et al.
2006/0036324 A1 2/2006 Sachs et al.
2006/0047282 A1 3/2006 Gordon
2006/0058790 A1 3/2006 Carl et al.
2006/0058791 A1 3/2006 Broman et al.
2006/0058792 A1 3/2006 Hynes
2006/0064091 A1 3/2006 Ludwig et al.
2006/0084976 A1 4/2006 Borgstrom et al.
2006/0084996 A1 4/2006 Metz-Stavenhagen
2006/0085075 A1* 4/2006 McLeer A61F 2/4405
623/17.12
2006/0089646 A1* 4/2006 Bonutti A61B 17/0218
606/279
2006/0116686 A1 6/2006 Crozet
2006/0142758 A1 6/2006 Petit
2006/0142760 A1 6/2006 McDonnell
2006/0149234 A1 7/2006 de Coninck
2006/0189984 A1 8/2006 Fallin et al.
2006/0190081 A1* 8/2006 Kraus A61B 17/7064
623/17.11
2006/0200149 A1 9/2006 Hoy et al.
2006/0212034 A1 9/2006 Triplett et al.
2006/0217712 A1 9/2006 Mueller et al.
2006/0217715 A1 9/2006 Serhan et al.
2006/0217718 A1 9/2006 Chervitz et al.
2006/0229616 A1 10/2006 Albert et al.
2006/0241594 A1 10/2006 McCarthy et al.
2006/0241598 A1 10/2006 Khalili
2006/0247627 A1 11/2006 Farris
2006/0247633 A1* 11/2006 Winslow A61B 17/025
606/247
2006/0247650 A1* 11/2006 Yerby A61B 17/025
606/90
2006/0247773 A1* 11/2006 Stamp A61B 5/076
623/17.11
2006/0253118 A1 11/2006 Bailey
2006/0271050 A1 11/2006 Piza Vallespir
2006/0276787 A1 12/2006 Zubok et al.
2006/0276790 A1* 12/2006 Dawson A61F 2/4405
606/86 A
2006/0293663 A1 12/2006 Walkenhorst et al.
2007/0005062 A1 1/2007 Lange et al.
2007/0016296 A1 1/2007 Triplett et al.
2007/0055373 A1 3/2007 Hudgins et al.
2007/0073293 A1 3/2007 Martz et al.
2007/0079517 A1 4/2007 Augostino et al.
2007/0083200 A1 4/2007 Gittings et al.
2007/0093814 A1 4/2007 Callahan et al.
2007/0093833 A1 4/2007 Kuiper et al.
2007/0161987 A1 7/2007 Capote et al.
2007/0161993 A1 7/2007 Lowery et al.
2007/0161994 A1 7/2007 Lowery et al.
2007/0162002 A1 7/2007 Tornier
2007/0167946 A1 7/2007 Triplett et al.
2007/0167947 A1 7/2007 Gittings
2007/0168035 A1 7/2007 Koske
2007/0179493 A1* 8/2007 Kim A61B 17/7062
606/33
2007/0185492 A1 8/2007 Chervitz et al.
2007/0191846 A1 8/2007 Bruneau et al.
2007/0198014 A1 8/2007 Graf et al.
2007/0213716 A1 9/2007 Lenke et al.
2007/0219556 A1 9/2007 Altarac et al.
2007/0225712 A1 9/2007 Altarac et al.
2007/0225713 A1 9/2007 Altarac et al.
2007/0233075 A1 10/2007 Dawson
2007/0233090 A1 10/2007 Naifeh et al.
2007/0233093 A1 10/2007 Falahee
2007/0238335 A1 10/2007 Veldman et al.
2007/0270803 A1 11/2007 Giger et al.
2007/0270805 A1 11/2007 Miller et al.
2007/0270817 A1 11/2007 Rezach
2007/0270836 A1 11/2007 Bruneau et al.
2007/0270837 A1 11/2007 Eckhardt et al.
2007/0270838 A1 11/2007 Bruneau et al.
2007/0270967 A1 11/2007 Fallin et al.
2007/0276374 A1 11/2007 Broman et al.
2007/0288011 A1 12/2007 Logan
2007/0288024 A1 12/2007 Gollogly
2008/0015577 A1 1/2008 Loeb
2008/0021466 A1 1/2008 Shadduck et al.
2008/0021469 A1 1/2008 Holt
2008/0027436 A1 1/2008 Cournoyer et al.
2008/0045954 A1 2/2008 Reiley et al.
2008/0065069 A1 3/2008 Betz et al.
2008/0077143 A1 3/2008 Shluzas
2008/0086213 A1 4/2008 Reiley
2008/0091202 A1 4/2008 Reiley
2008/0091210 A1 4/2008 Reiley
2008/0091268 A1 4/2008 Reiley
2008/0097437 A1 4/2008 Reiley
2008/0097438 A1 4/2008 Reiley
2008/0097439 A1 4/2008 Reiley
2008/0097440 A1 4/2008 Reiley et al.
2008/0097441 A1 4/2008 Hayes et al.
2008/0097446 A1 4/2008 Reiley et al.
2008/0097609 A1 4/2008 Reiley
2008/0097612 A1 4/2008 Reiley
2008/0097613 A1 4/2008 Reiley et al.
2008/0132951 A1 6/2008 Reiley et al.
2008/0140202 A1 6/2008 Allard et al.
2008/0167688 A1 7/2008 Fauth et al.
2008/0177326 A1 7/2008 Thompson
2008/0177392 A1* 7/2008 Williams A61F 2/441
623/17.16
2008/0183209 A1 7/2008 Robinson et al.
2008/0183212 A1 7/2008 Veldman et al.
2008/0195100 A1 8/2008 Capote et al.
2008/0195153 A1 8/2008 Thompson
2008/0195154 A1 8/2008 Brown et al.
2008/0200953 A1 8/2008 Reiley et al.
2008/0221622 A1 9/2008 Triplett et al.
2008/0228227 A1 9/2008 Brown et al.
2008/0234737 A1 9/2008 Boschert

(56) **References Cited**

U.S. PATENT DOCUMENTS

2008/0234739 A1	9/2008	Hudgins et al.	
2008/0262546 A1	10/2008	Calvosa et al.	
2008/0269805 A1	10/2008	Dekutoski et al.	
2008/0275507 A1	11/2008	Triplett et al.	
2008/0292161 A1	11/2008	Funk et al.	
2008/0306535 A1	12/2008	Winslow et al.	
2008/0306536 A1	12/2008	Frigg et al.	
2008/0319483 A1	12/2008	Triplett et al.	
2008/0319484 A1	12/2008	Fauth	
2008/0319485 A1	12/2008	Fauth et al.	
2008/0319488 A1	12/2008	Helgerson	
2008/0319489 A1	12/2008	Triplett	
2009/0012565 A1	1/2009	Sachs et al.	
2009/0012566 A1	1/2009	Fauth	
2009/0018583 A1	1/2009	Song et al.	
2009/0024134 A1	1/2009	Triplett et al.	
2009/0024135 A1	1/2009	Triplett et al.	
2009/0024166 A1	1/2009	Carl et al.	
2009/0024167 A1	1/2009	Chervitz et al.	
2009/0024168 A1	1/2009	Chervitz et al.	
2009/0024169 A1	1/2009	Triplett et al.	
2009/0030459 A1	1/2009	Hoy et al.	
2009/0030460 A1	1/2009	Chervitz et al.	
2009/0030461 A1	1/2009	Hoy et al.	
2009/0036929 A1	2/2009	Reglos et al.	
2009/0048632 A1	2/2009	Firkins et al.	
2009/0062864 A1	3/2009	Ludwig et al.	
2009/0062915 A1	3/2009	Kohm et al.	
2009/0069849 A1	3/2009	Oh et al.	
2009/0082871 A1	3/2009	Fallin et al.	
2009/0088802 A1	4/2009	Fallin	
2009/0093820 A1	4/2009	Trieu et al.	
2009/0099607 A1	4/2009	Fallin et al.	
2009/0112207 A1	4/2009	Walker et al.	
2009/0112262 A1	4/2009	Pool et al.	
2009/0112263 A1	4/2009	Pool et al.	
2009/0125062 A1	5/2009	Arnin	
2009/0132050 A1*	5/2009	Holm	A61F 2/30942 623/17.16
2009/0194206 A1	8/2009	Jeon et al.	
2009/0204156 A1	8/2009	McClintock et al.	
2009/0216331 A1*	8/2009	Grotz	A61F 2/442 623/17.16
2009/0234456 A1*	9/2009	Nycz	A61F 2/442 623/17.16
2009/0259256 A1	10/2009	Miller	
2009/0281575 A1	11/2009	Carls et al.	
2010/0057129 A1	3/2010	Goble et al.	
2010/0076493 A1	3/2010	Fauth et al.	
2010/0082107 A1	4/2010	Fauth et al.	
2010/0087880 A1	4/2010	Fauth et al.	
2010/0100130 A1	4/2010	Carl et al.	
2010/0100133 A1	4/2010	Carl et al.	
2010/0100185 A1*	4/2010	Trieu	A61F 2/4425 623/17.16
2010/0106192 A1	4/2010	Barry	
2010/0137913 A1	6/2010	Khatchadourian et al.	
2010/0168864 A1*	7/2010	White	A61B 17/06114 623/18.11
2010/0191100 A1*	7/2010	Anderson	A61B 5/055 600/424
2010/0204802 A1*	8/2010	Wilson	A61B 5/0031 623/23.6
2010/0249836 A1	9/2010	Seme	
2010/0249837 A1	9/2010	Seme et al.	
2010/0256684 A1	10/2010	Seme et al.	
2010/0274286 A1	10/2010	Blain et al.	
2010/0286730 A1	11/2010	Gordon	
2010/0318129 A1	12/2010	Seme et al.	
2011/0054536 A1	3/2011	Elsebaie et al.	
2011/0060367 A1	3/2011	Stauber	
2011/0066188 A1	3/2011	Seme et al.	
2011/0245876 A1	10/2011	Brumfield	
2012/0221057 A1	8/2012	Zhang et al.	
2013/0079793 A1*	3/2013	Stein	A61F 2/4657 606/102
2013/0103156 A1*	4/2013	Packer	A61F 2/442 623/17.16
2013/0123851 A1	5/2013	Seme et al.	
2013/0123853 A1	5/2013	Seme et al.	
2013/0150970 A1*	6/2013	Thaiyananthan	A61F 2/442 623/17.16
2013/0184757 A1	7/2013	Seme et al.	
2013/0204157 A1*	8/2013	Clark	A61B 5/4576 600/547
2013/0211455 A1	8/2013	Seme	
2013/0231703 A1	9/2013	Seme et al.	
2015/0257799 A1*	9/2015	Janna	A61F 5/05 606/328
2015/0282797 A1*	10/2015	O'Neil	A61B 17/025 606/279
2015/0297362 A1*	10/2015	Singh	A61F 2/4657 623/22.15

FOREIGN PATENT DOCUMENTS

DE	10135771	*	2/2003	A61B 17/7064
EP	0260044	A1	3/1988	
EP	0322334	A1	6/1989	
EP	0418387	A1	3/1991	
EP	1281361	A1	2/2003	
FR	2697744	A1	5/1994	
FR	2736535	A1	1/1997	
FR	2781359	A1	1/2000	
FR	2801492	A1	6/2001	
FR	2872021	A1	12/2005	
FR	2900563	A1	11/2007	
GB	780652	A	8/1957	
SU	888968	A1	12/1981	
WO	9213496	A1	8/1992	
WO	2004017705	A2	3/2004	
WO	2006010844	A1	2/2006	
WO	2006017641	A2	2/2006	
WO	2006136937	A2	12/2006	
WO	2007051924	A1	5/2007	
WO	2008086467	A2	7/2008	
WO	2008154313	A1	12/2008	
WO	2010053662	A1	5/2010	
WO	2010056650	A1	5/2010	
WO	2010111500	A2	9/2010	

OTHER PUBLICATIONS

Berry, James L. et al., A Morphometric Study of Human Lumbar and Selected Thoracic Vertebrae, 12 Spine 362 (1987).

Fujita, Masaru et al., A Biomechanical Analysis of Sublaminar and Subtransverse Process Fixation Using Metal Wires and Polyethylene Cables, 31 Spine 2202 (2006).

Girardi, Federico R et al., Safety of Sublaminar Wires With Isola Instrumentation for the Treatment of Idiopathic Scoliosis, 25 Spine 691 (2000).

International Application No. PCT/US2008/065979, filed Jun. 5, 2008, entitled Medical Device and Method to Correct Deformity.

International Application No. PCT/US2009/063833, filed Nov. 10, 2009, entitled Growth Directed Vertebral Fixation System With Distractible Connector(s) and Apical Control.

International Application No. PCT/US2010/028684, filed Mar. 25, 2010, entitled Semi-Constrained Anchoring System.

International Search Report and Written Opinion issued in PCT/US2005/027692, mailed May 19, 2008, 4 pages.

International Search Report and Written Opinion issued in PCT/US2008/065979, mailed Oct. 2, 2008, 7 pages.

International Search Report and Written Opinion issued in PCT/US2009/063833, mailed Mar. 15, 2010, 14 pages.

International Search Report and Written Opinion issued in PCT/US2010/028684, mailed Sep. 28, 2010, 19 pages.

International Search Report and Written Opinion issued in PCT/US2010/036375, mailed Sep. 10, 2010, 16 pages.

International Search Report and Written Opinion issued in PCT/US2010/047117, mailed Dec. 2, 2010.

(56) **References Cited**

OTHER PUBLICATIONS

International Search Report and Written Opinion issued in PCT/US2011/049693, mailed Nov. 15, 2011, 16 pages.
Invitation to Pay Additional Fees and Partial Search Report issued in PCT/US2010/028684, mailed Jun. 30, 2010, 6 pages.
Liljenqvist, Ulf R. et al., Analysis of Vertebral Morphology in Idiopathic Scoliosis with Use of Magnetic Resonance Imaging and Multiplanar Reconstruction, 84 J Bone Joint Surg Am. 359 (2002).
Molnar, Szabolcs et al., Ex Vivo and in Vitro Determination of the Axial Rotational Axis of the Human Thoracic Spine, 31 Spine E984 (2006).
Rajasekaran, S. et al., Eighteen-Level Analysis of Vertebral Rotation Following Harrington-Luque Instrumentation in Idiopathic Scoliosis, 76 J Bone Joint Surg Am. 104 (1994).
U.S. Appl. No. 12/411,558, filed Mar. 26, 2009, entitled Alignment System With Longitudinal Support Features.
U.S. Appl. No. 12/411,562, filed Mar. 26, 2009, entitled Semi-Constrained Anchoring System.
U.S. Appl. No. 12/485,796, filed Jun. 16, 2009 entitled Deformity Alignment System With Reactive Force Balancing.
U.S. Appl. No. 12/560,199, filed Sep. 15, 2009, entitled Growth Modulation System.
Wenger, Dennis R. et al., Biomechanics of Scoliosis Correction by Segmental Spinal Instrumentation, 7 Spine 260 (1982).
White III, Augustus A. et al., Biomechancis of the Spine 28-29, Tbl. 1-5 (2d ed. 1990).
European Search Report issued in EP Application No. 12154799, completed Mar. 2, 2012, 9 pages.
International Search Report and Written Opinion issued in PCT/US2012/065262, mailed Feb. 5, 2013, 8 pages.
International Search Report and Written Opinion issued in PCT/US2012/040493, mailed Aug. 21, 2012, 15 pages.
International Search Report and Written Opinion issued in PCT/US2013/065488, mailed Feb. 18, 2014, 10 pages.
Eglin, D. et al., “Degradable Polymeric Materials for Osteosynthesis: tutorial”, European Cells and Materials, vol. 16, 2008, pp. 80-91.
Girardi, Federico P. et al., Safety of Sublaminar Wires With Isola Instrumentation for the Treatment of Idiopathic Scoliosis, 25 SPINE 691 (2000).
International Application No. PCT/US2010/28684, filed Mar. 25, 2010, entitled Semi-Constrained Anchoring System.

* cited by examiner

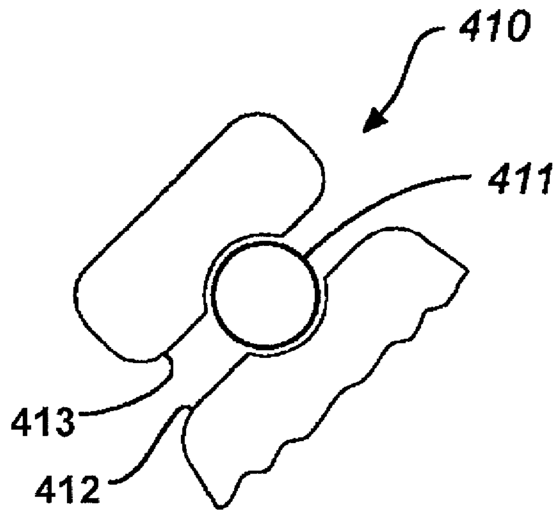


FIG. 1

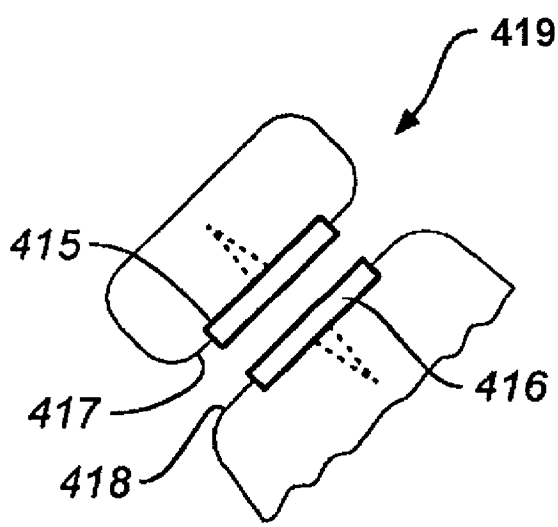
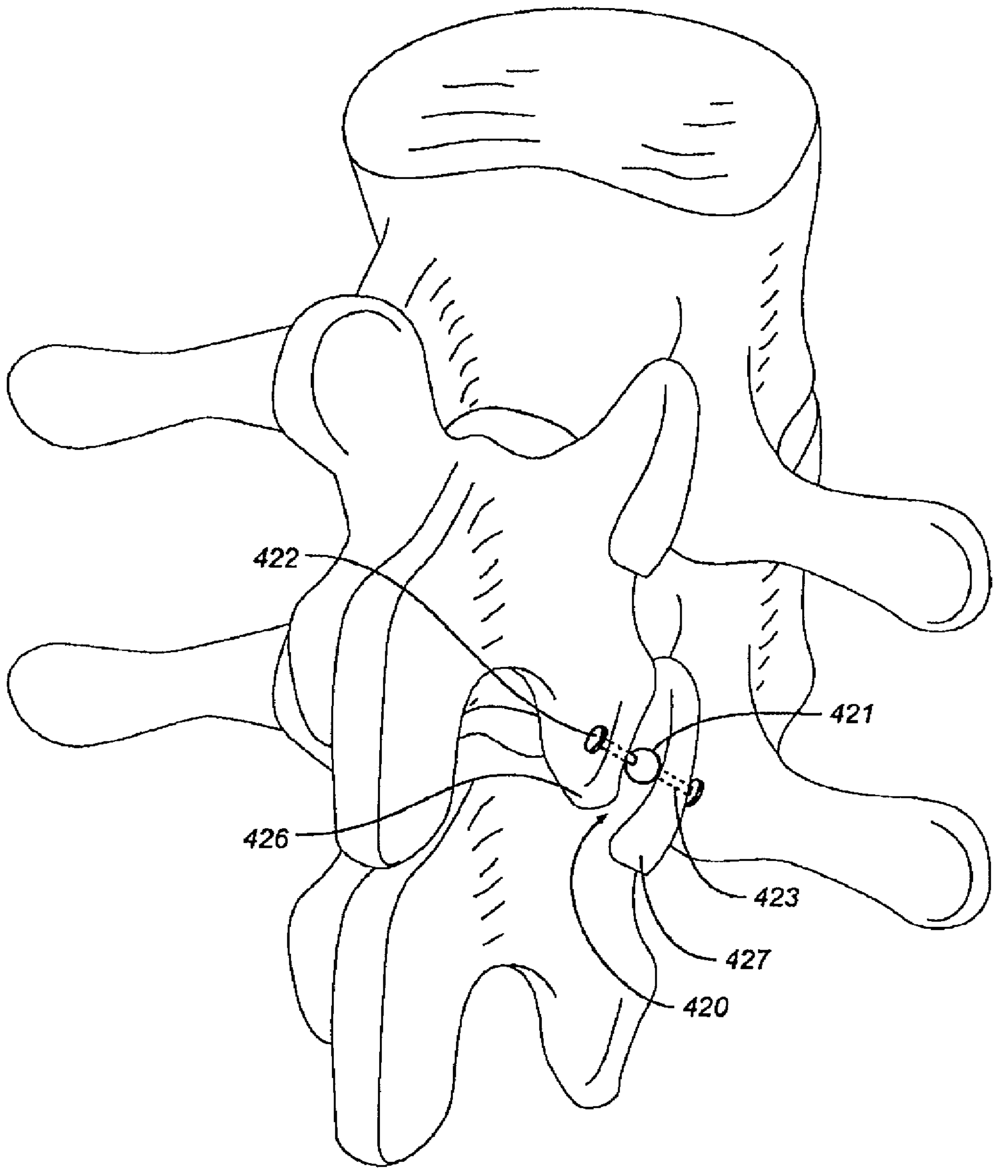


FIG. 2



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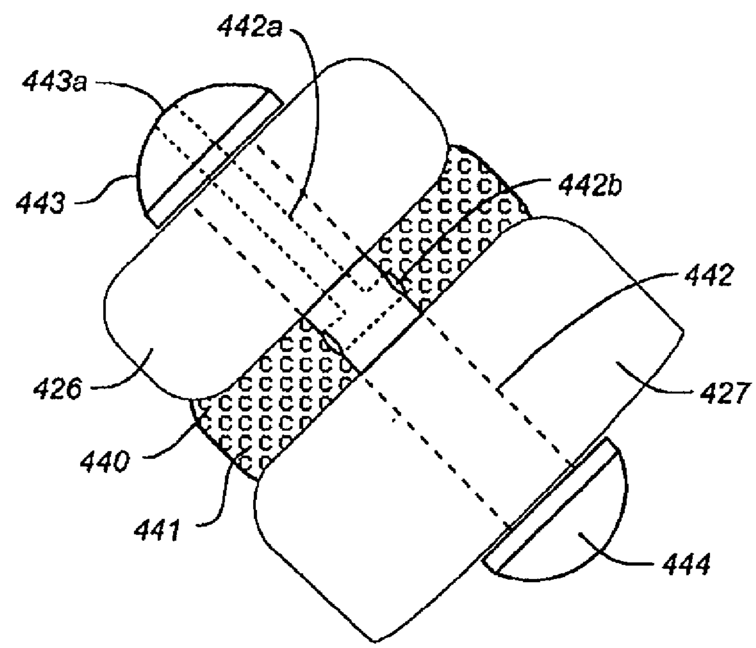
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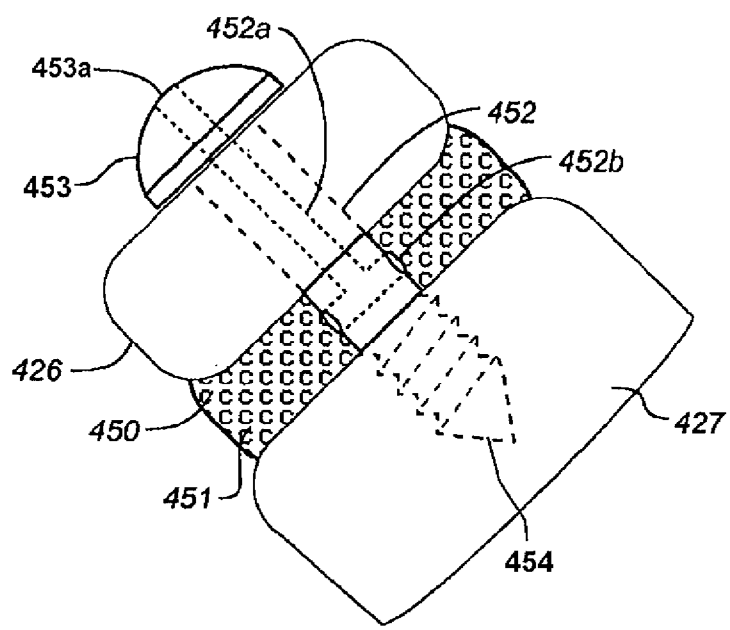
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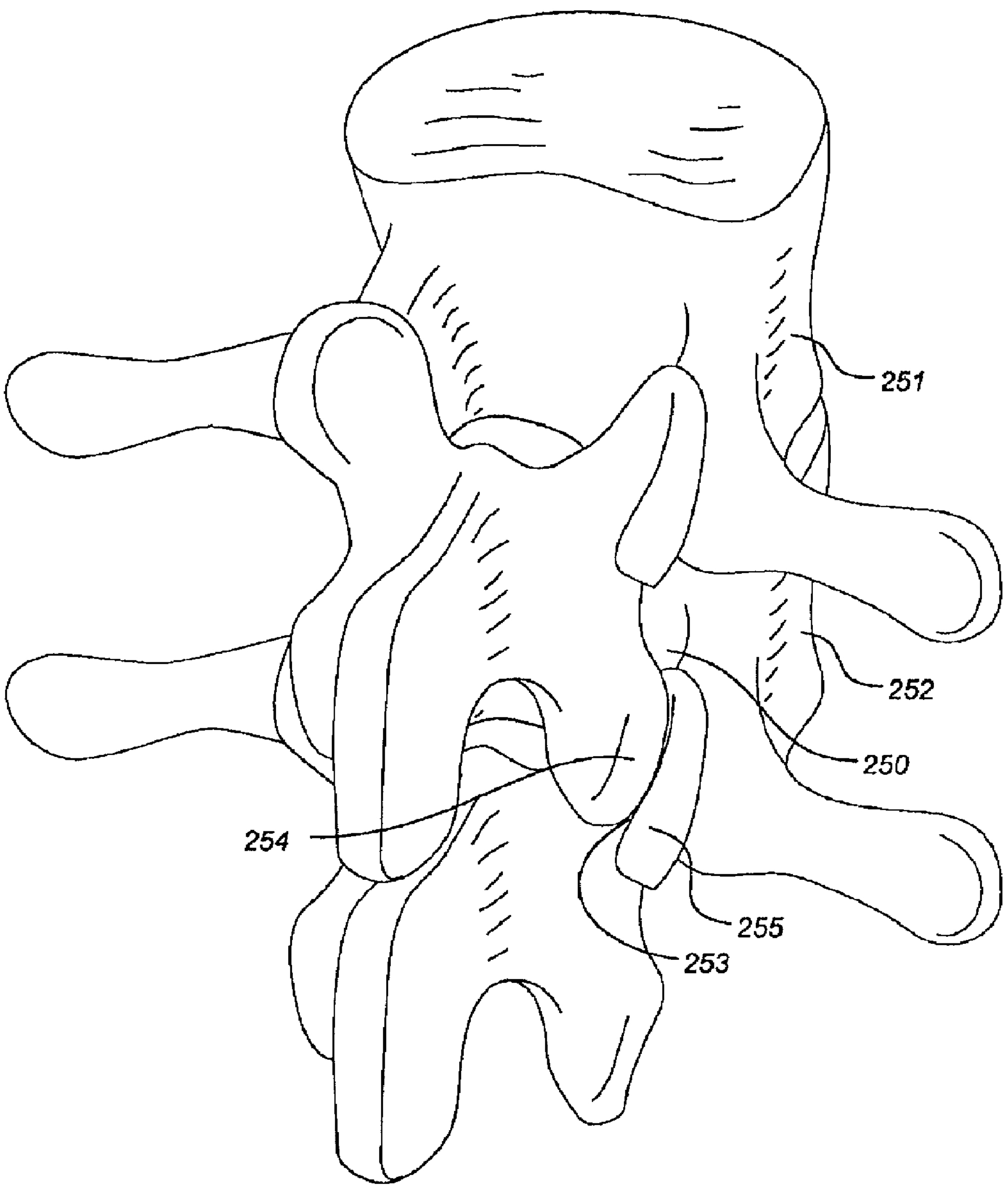
FIG. 5



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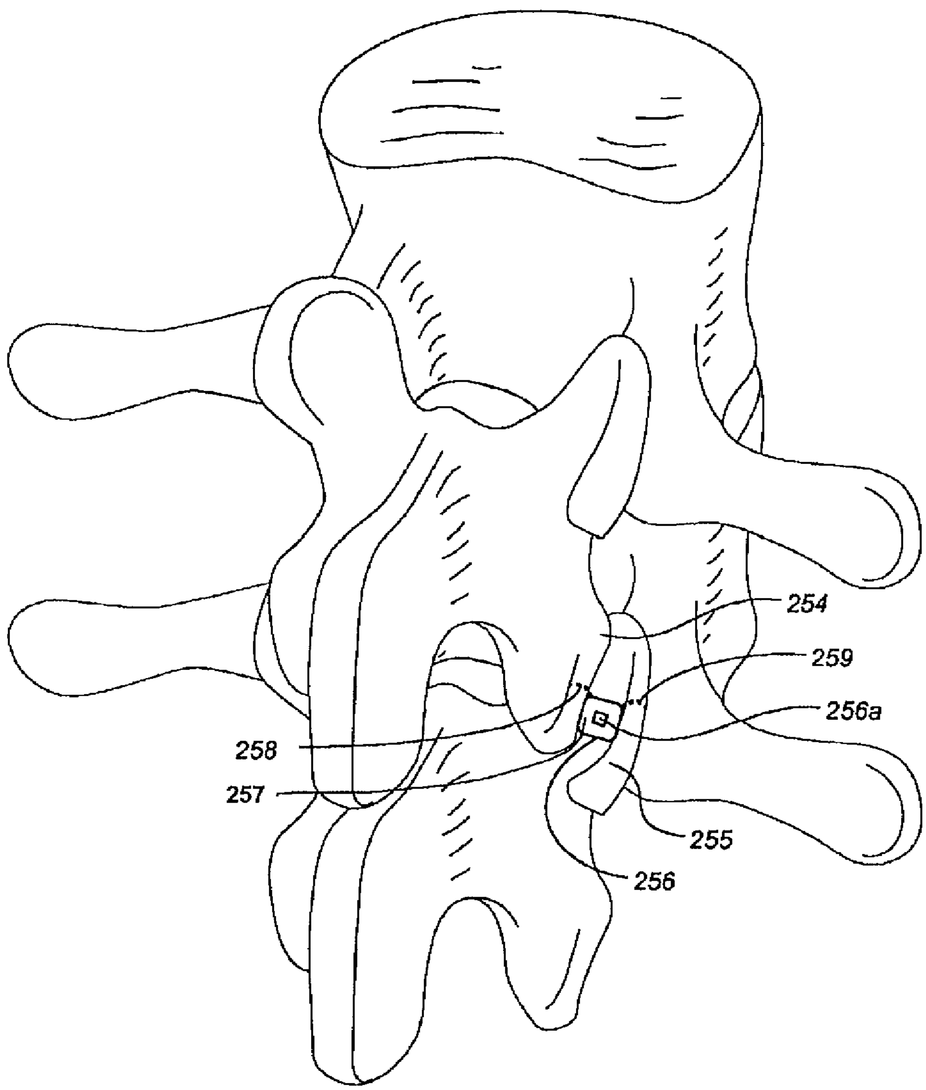


FIG. 7

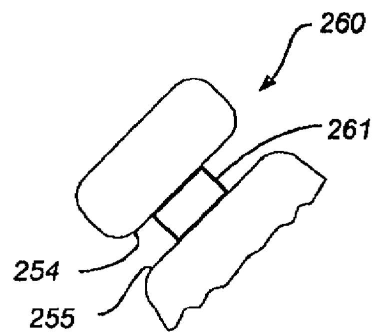


FIG. 8

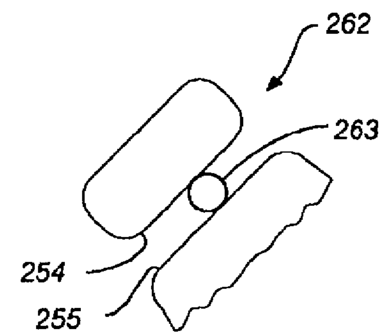
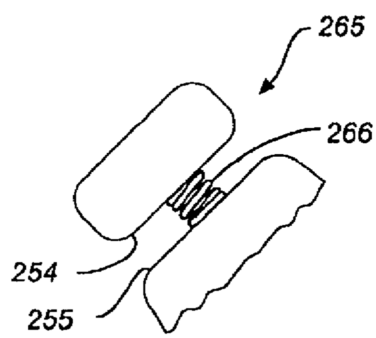


FIG. 9



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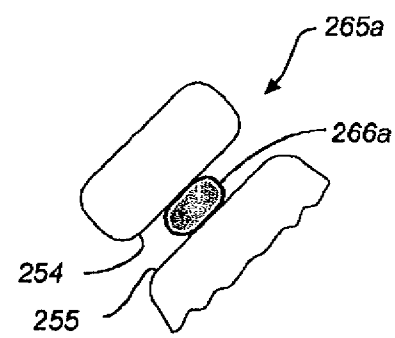

FIG. 11

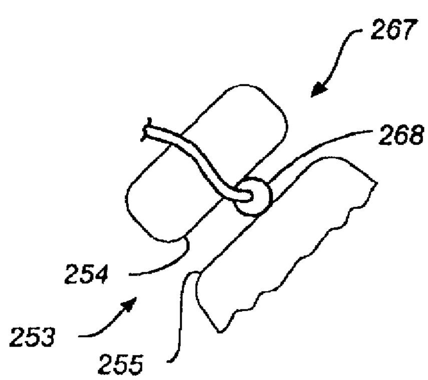

FIG. 12

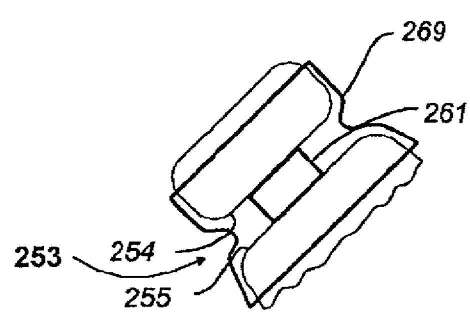

FIG. 13

FACET DEVICE AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a divisional of application Ser. No. 13/346,435, filed Jan. 9, 2012 and entitled "Facet Device and Method," which is a continuation of application Ser. No. 12/169,370, filed Jul. 8, 2008 and entitled "Facet Device and Method," now U.S. Pat. No. 8,114,158, which is a continuation-in-part of application Ser. No. 11/197,566, filed Aug. 3, 2005 and entitled "Facet Device and Method," now abandoned, which claims the benefit of U.S. Provisional Application No. 60/598,882, filed Aug. 3, 2004 and entitled "Spine Treatment Devices and Methods," all of which are incorporated by reference herein in their entireties for all purposes.

FIELD OF THE INVENTION

The invention relates to devices to treat the spine, in particular in association with a facet joint, including but not limited to spinal stabilization devices, spinal distraction devices, spinal prostheses, devices to treat pain associated with the spine, and other spinal treatment devices.

DESCRIPTION OF THE RELATED ART

Certain spine conditions, defects, deformities (e.g., scoliosis) as well as injuries may lead to structural instabilities, nerve or spinal cord damage, pain or other manifestations. Back pain (e.g., pain associated with the spinal column or mechanical back pain) may be caused by structural defects, by injuries or over the course of time from the aging process. For example, back pain is frequently caused by repetitive and/or high stress loads on or increased motion around certain boney or soft tissue structures. The natural course of aging leads to degeneration of the disc, loss of disc height, and instability of the spine among other structural manifestations at or around the spine. With disc degeneration, the posterior elements of the spine bear increased loads with disc height loss, and subsequently attempt to compensate with the formation of osteophytes and thickening of various stabilizing spinal ligaments. The facet joints may develop pain due to arthritic changes caused by increased loads. Furthermore, osteophytes in the neural foramina and thickening of spinal ligaments can lead to spinal stenosis, or impingement of nerve roots in the spinal canal or neural foramina. Scoliosis also creates disproportionate loading on various elements of the spine and may require correction, stabilization or fusion.

Pain caused by abnormal motion of the spine has long been treated by fixation of the motion segment. Spinal fusion is one way of stabilizing the spine to reduce pain. In general, it is believed that anterior interbody or posterior fusion prevents movement between one or more joints where pain is occurring from irritating motion. Fusion typically involves removal of the native disc, packing bone graft material into the resulting intervertebral space, and anterior stabilization, e.g., with intervertebral fusion cages or posterior stabilization, e.g., supporting the spinal column with internal fixation devices such as rods and screws. Internal fixation is typically an adjunct to attain intervertebral fusion. Many types of spine implants are available for performing spinal fixation, including the Harrington hook and rod, pedicle screws and rods, interbody fusion cages, and sublaminar wires.

Alternatives have been proposed and tested to replace the need for spinal fusion to treat patients with back pain. These implants include artificial discs and artificial nucleus technologies that preserve motion. However, these implants do not directly address the forces borne by the facet joints.

The facet joints provide a means for load transmission, support and motion of the posterior spinal column. Disc height loss from degenerative disc disease and aging leads to increased load on the facet joints, which can lead to arthritic, painful, degenerative changes.

Often over the course of degenerative disc disease there is a narrowing of the neural foramen through which the nerves exit the spine. In addition to the degeneration of discs causing the narrowing of the foramen, there is also calcification around the foramen causing further narrowing or stenosis resulting in pain to the patient. Currently, these conditions may be treated by removing some or all of the lamina (laminectomy) or posterior bone adjacent or around the stenotic neural foramen

Given that the facet joint and its environs is a source of pain for some patients, some procedures have been developed or proposed to relieve pain associated with the facet joint. Partial or complete removal of the pathological facets, and replacement with a mechanical joint that preserves motion similar to a facet has been proposed. Additionally, individual degenerative facet articulations have been replaced with caps.

It would be desirable to provide improved devices and methods for relieving pain associated with the facet joints.

Spinal stenosis pain or from impingement of nerve roots in the neural foramina has been treated by laminectomy and foraminotomy, and sometimes reinforced with rod and screw fixation of the posterior spine.

More recently, as an alternative to laminectomies and related procedures, implants have been proposed that distract the spine from a posterior approach. In particular, a wedge-like implant inserted between two adjacent spinous processes has been proposed to relieve pressure on spinal nerves and nerve roots. A kyphosis is induced, which opens the space of the spinal canal and neural foramen, thereby reducing the effect of spinal stenosis. However, this type of distraction of adjacent spinous processes is suboptimal for several reasons: The resulting kyphosis is non-physiologic, leading to increased load on the anterior portion of the disc and the vertebral bodies. This can increase the risk of disc degeneration and vertebral compression fracture. The implant tends to bend the spine forward. The spinous processes may fracture due to the distraction forces of the wedge implant. Bone may collapse around the spinous process. The implant may weaken, tear, or stretch stabilizing ligaments of the spine, such as the supraspinous ligament, interspinous ligament, ligamentum flavum, posterior longitudinal ligament, or capsule of the zygapophyseal joint. The amount of distraction is not adjustable to the specific amount of stenosis, and cannot be easily readjusted months to years after the device has been implanted.

It would accordingly be desirable to provide a distraction device that reduces or avoids some or all of these issues.

Pain due to instability of the spine has also been treated with dynamic stabilization of the posterior spine, using elastic bands that connect pedicles of adjacent vertebrae.

The typical techniques for fusion, decompression, and dynamic stabilization require open surgical procedures with removal of stabilizing muscles from the spinal column, leading to pain, blood loss, and prolonged recovery periods after surgery due in part to the disruption of associated body structures or tissue during the procedures.

Accordingly, it would be desirable to provide less invasive devices and methods for treating pain or discomfort associated with the spinal column. It would also be desirable to provide such devices and methods that are less damaging to associated tissue.

Spine surgeons commonly use metallic or polymeric implants to effect or augment the biomechanics of the spine. The implants frequently are attached or anchored to bone of the spine. Sites typically considered appropriate for boney attachment have high density or surface area, such as, for example, the pedicle bone, the vertebral body or the cortical bone of the lamina. The spinous process contains thin walls of cortical bone, and thus, has been considered as not ideal for anchoring spinal implants as they may not support the implants under physiologic loads, or the intermittent high loads seen in traumatic situations. Fixation has been attempted from spinous process to spinous process with poor results.

A translaminar facet screw as used by some surgeons goes through the base of spinous process to access the cancellous bone of the lamina. A disadvantage of this device is that it is not suitable for attaching to a pedicle screw and the depth and angle during deployment can be very difficult to track or visualize, thus increasing the possibility that the screw would extend into the spinal canal. A facet screw is screwed between opposing facets of a zygapophyseal joint.

SUMMARY OF THE INVENTION

One aspect of the present invention is directed to providing a device and method for alleviating discomfort and or deformity associated with the spinal column. Another aspect of the present invention is directed to providing a minimally invasive implant and method for alleviating discomfort associated with the spinal column. Another aspect of the present invention provides an anchoring device and method that requires less surrounding tissue damage or disruption. Other aspects of the invention may supplement or bear load for degenerated or painful joints, e.g., the facet joint.

One aspect of the invention provides for repair or reconstruction of a dysfunctional facet joint. For example, by entering the capsule of the facet joint, creating a space between articulating facets by removing synovium, cartilage, and some bone from within the zygapophysial joint, and, then, inserting a motion preserving prosthesis. Motion preserving prostheses may include a smooth and/or curved surface, a sphere, an egg shaped/oval implant, or a self contained "ball and socket" joint. Magnetic plates with like poles facing each other may be attached to interfacing articulating portions of the facets. Attachment of the motion preserving prosthesis may involve extensions from the prosthesis that partially or completely penetrate each of the facets.

Another aspect of the invention provides for repairing the encapsulating ligaments with suture, adhesive, a patch, or other materials after a capsule of the zygapophysial joint has been invaded for tissue removal and insertion of a prosthesis. One aspect of the invention includes an elastic encapsulating wrap used to stabilize the facet joints.

According to an embodiment of the invention, a facet distraction implant is provided for maintaining a space that is formed between the facet articulations of adjacent vertebrae when the joints are distracted. The facets may be distracted using a known distraction method or technique and an implant may be placed between the facets. A securing device according to the invention may be positioned to anchor each of the facet articulations of a facet joint to each other in distraction to maintain the opening of the corresponding neural foramen. The prosthesis may include a distraction element that exerts a distracting force on the joint.

Various aspects of the invention are set forth in the description and/or claims herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic side view of a facet implant in accordance with the invention.

FIG. **2** is a schematic side view of a facet implant in accordance with the invention.

FIG. **3** is a schematic posterior lateral perspective view of a facet implant in accordance with the invention.

FIG. **4** is a side partial cross section of a facet implant in accordance with the invention.

FIG. **5** is a side partial cross section of a facet implant in accordance with the invention.

FIG. **6** is a schematic posterior lateral perspective view of a stenotic neural foramen of a posterior spine.

FIG. **7** is a schematic posterior lateral view of a facet implant in accordance with the invention.

FIG. **8** is a side schematic view of a facet implant in accordance with the invention.

FIG. **9** is a side schematic view of a facet implant in accordance with the invention.

FIG. **10** is a side schematic view of a facet implant in accordance with the invention.

FIG. **11** is a side schematic view of a facet implant in accordance with the invention.

FIG. **12** is a side schematic view of a facet implant in accordance with the invention.

FIG. **13** is a side schematic view of a facet implant in accordance with the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGS. **1-5** illustrate facet repair prostheses in accordance with an embodiment of the invention. Prosthesis **410** comprises a ball bearing **411** implanted between the caudal and the cephalic facets **412**, **413** of the zygapopyhseal joint. (FIG. **1**) The joint is prepared by removing soft tissue between the joints and creating a concavity on adjacent facet plates for receiving the ball bearing.

In FIG. **2**, magnets **415**, **416** including smooth interacting bearing surfaces are respectively screwed into the cephalic and caudal facets **417**, **418** of the zygapopyhseal joint **419**. The magnets **415**, **416** are oriented so that like poles face each other (e.g. North-North or South-South) to provide a distraction force at the joint. The magnets may have a center hole through which a rod is inserted to resist the tendency of one magnet to move relative to the other. Each end of the rod may have a diameter larger than the center holes. This system may be used in other joints in the body to maintain separation between the joints.

Referring to FIG. **3**, a joint prosthesis **420** is positioned between the cephalic and caudal facets **426**, **427**. The prosthesis comprises a ball **421** providing a bearing surface for the motion of the facets **426**, **427**, and opposing posts **422**, **423** screwed in or otherwise implanted in the facets **426**, **427**, respectively for securing the ball **421** within the joint. The ball **421** may include openings for receiving the posts, e.g., in a tapered interference type fitting, to secure the posts **422**, **423** to the ball **421** and to secure the ball **421** within the joint.

This facet repair may be performed percutaneously or via minimally invasive surgical techniques, for example using percutaneously positioned distracting instruments to distract the joint, for example, an expanding balloon or forceps like distractors. Using a hollow needle percutaneously positioned into the joint, an expandable or self-expanding facet distraction implant may be placed in position through the hollow lumen of the needle into the joint. A polymer material may be injected into the joint through a percutaneously inserted needle.

FIG. **4** illustrates a material **440** such as a polymer injected between the cephalic and caudal facets **426**, **427**. The material **440** forms a flexible member **441** that allows some movement of the joint due to the flexible properties and/or the shape that permit articulation of the joint. A securing member **442** extends through the facets **426**, **427** and the material **440** to further hold the member **441** in place in the joint capsule and/or to prevent implant extrusion. The securing member **442** includes anchors **443**, **444** that anchor to the outside or within the facets **426**, **427** to hold the securing member **442** in place while permitting some motion for example through spacing at or in the joint. The securing member **442** may for example, comprise a screw, or may be constructed of a flexible material such as a flexible polymer. The securing member may also comprise a band constructed of fibers strands such as Kevlar™, polypropylene or polyethylene, or constructed of a fiber reinforced polymer. The anchors **443**, **444** may be of a material such as titanium, or PEAK that may be screwed or crimped on to the securing member **442**. The polymer may be injected into the joint capsule into opening **443***a* in the anchor **443**, through a lumen **442***a* in the securing member **442** and through holes **442***b* or pores in the securing member **442**. This may be done when the joint is distracted or otherwise positioned as desired.

FIG. **5** illustrates a material **450** such as a polymer injected between the cephalic and caudal facets **426**, **427**. The material **450** forms an implant **451** that allows some movement of the joint due to the flexible properties and/or a shape that permits articulation of the joint. A securing member **452** extends through the facets **426**, **427** and the material **450** to further hold the implant **451** in place in the joint capsule. The securing member **452** includes an anchor **453** that anchors the member to the outside or within the facet **426**, (or alternatively to the outside or within the facet **427**) to hold the securing member **452** in place. The securing member **452** further includes a tapered end that allows the securing member **452** to be inserted through the joint capsule and anchored into facet **427**. The securing member may be a screw with a threaded tip **454** that screws into the bone. The securing member can further include a flexible portion that allows some movement of the securing member and joint. The anchor **453** may include an opening **453***a* into a lumen **452***a* in the securing member **452**, for injecting a polymer into a lumen **452***a* in the member and then through holes **452***b* into the joint capsule to form the implant **451**.

According to the invention, a facet joint device as described herein may be used in combination with an artificial disc or other spinal implants, e.g., to maintain the integrity of the facets. The facet joint distraction or replacement devices and procedures described herein may be used in conjunction with anteriorly placed implants, e.g., in a load sharing arrangement. The facet joint resurfacing, distraction or augmentation as well as the anterior implants may be used with a process to pedicle distraction or stabilizing device as

described herein. Various spinal implants may also be used with facet resurfacing, facet distraction or augmentation procedures.

In accordance with one aspect of the invention, narrowing or stenosis of the neural foramen may be treated using a device configured to distract the facet joint. Accordingly, a distraction system is provided for distracting the facet joint.

Referring to FIG. **6**, a portion of the spine is illustrated with adjoining vertebrae prior to distraction. The neural foramen **250** between a first vertebra **251** and a second vertebra **252** is stenotic. At the zygapophyseal joint capsule **253**, there is no gap between the cephalic and caudal facets **254**, **255**.

Referring to FIG. **7**, the portion of the spine of FIG. **6** is illustrated with a facet distracter implant **256** in place between the cephalic facet **254** and the caudal facet **255**. The implant **256** comprises a distracting portion **257** and anchors **258**, **259** comprising barbs or bone anchors. The distracting portion may include a distracting element as described with respect to FIGS. **8-13** herein. The anchor **258** is positioned in bone above the cephalic facet **254** while the anchor **259** is positioned in the bone below the caudal facet **255**. The facet distracter implant **256** includes a sensor **256***a*, the type of which may be selected to sense one of a number of different parameters. Pressure sensors, strain gauges, or other sensors may be used to sense load seen by the facet joint. This information may be used to monitor the condition of the facet joint or determine if fusion may be necessary. The other facet joint implants described herein may also include similar sensors.

The procedure for implanting the device generally includes opening the zygapophyseal joint capsule with a scalpel. Then the adjacent vertebrae are distracted by one of a number of known distraction methods or by distracting the joint mechanically using devices such as a wedge or expanding rod or balloon between adjacent spinous processes, or between other parts of adjacent vertebrae. The tissue between the facets **254**, **255** is then debrided and/or denervated. The implant is then inserted between the facets **254**, **255** after the joint is distracted. The anchors **258**, **259** engage the interfacing portions of the bone of the facets **254**, **255**.

FIG. **8** illustrates a distracter implant **260** positioned between facets **254**, **255**. The distracter implant **260** comprises a block **261** wedged between the facets **254**, **255**. In FIG. **9** an alternative distracter **262** implant comprises a ball **263**. In FIG. **10** an active distracter implant **265** comprise a coiled spring **266**. In FIG. **11**, the distracter implant **265***a* comprises an expandable polymer **266***a*, e.g., a hydrogel or expandable gel foam. In FIG. **12** the distracter implant **267** comprise an expandable member **268** that may be expanded to distract the joint **253** by inflating with a curable polymer, a liquid, gas or other material. The distraction may occur after implantation to adjust the level of distraction. The expandable member may also be adjusted after implanting by increasing or removing the inflation medium, e.g. using a needle or accessing the member through a one-way valve. FIG. **13** illustrates a shrink-wrap **269** placed partially around the joint **253**. The shrink-wrap or other material comprises, e.g., a Dacron material that holds the block **261** or other implant in place between facets **254**, **255**. The material may encourage ingrowth of tissue. The material may be coated with a material that reduces tissue ingrowth to permit the joint to move or reduces adhesions to prevent pain. The material may include burrs or barbs that secure the material to the bone or it may be secured, e.g. with suture anchors. The implants may be constructed, for example, of a metal, polymer or ceramic, may be coated or imbedded with therapeutic agents (e.g. a steroid or lidocaine) or other material.

What is claimed is:

1. A facet implant comprising:

an insert positionable between a first facet of a facet joint and a second facet of the facet joint, the insert configured to exert a distraction force on the first and second facets:

an anchor connected to the insert and configured to secure to one of the first and second facets;

a sensor coupled to the insert and configured to sense load on the facet joint; and

a shrink-wrap material secured at least partially around the insert,

wherein the shrink-wrap material includes burrs or barbs.

2. The facet implant of claim **1**, wherein the anchor includes a bone anchor.

3. The facet implant of claim **1**, wherein the anchor includes a barb.

4. The facet implant of claim **1**, further including a second anchor connected to the insert and configured to secure to the other of the first and second facets.

5. The facet implant of claim **1**, wherein the insert includes a block configured to wedge between the first and second facets.

6. The facet implant of claim **1**, wherein the insert includes a ball.

7. The facet implant of claim **1**, wherein the insert includes a coiled spring.

8. The facet implant of claim **1**, wherein the insert includes an expandable polymer.

9. The facet implant of claim **8**, wherein the expandable polymer includes a hydrogel, a gel foam, or combination thereof.

10. The facet implant of claim **1**, wherein the insert is configured to inflate and distract the facet joint when the insert receives an inflation medium therein while positioned within a facet joint capsule defined between the first and second facets, the inflation medium including a curable polymer, a liquid, a gas, or combination thereof.

11. The facet implant of claim **10**, wherein the inflation medium is selectively removable from the insert to adjust dimensions of the insert.

12. The facet implant of claim **1**, wherein the shrink-wrap material includes a polymeric material.

13. The facet implant of claim **1**, wherein the shrink-wrap material includes a coating adapted to reduce tissue ingrowth.

14. The facet implant of claim **1**, wherein the insert is formed of metal, polymer, ceramic, or combinations thereof.

15. The facet implant of claim **1**, wherein the insert contains a therapeutic agent.

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